

Notice of Allowability

Application No.

10/031,313

Examiner

Stacy B. Chen

Applicant(s)

HALLEK ET AL.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/22/07.
2. ☒ The allowed claim(s) is/are 91 and 94-100.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☒ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>1/22/07</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Karen Elbing on March 27, 2007.

IN THE SPECIFICATION:

Insert the following abstract on a separate page:

-- Abstract of the Invention

The invention relates to a structural protein of adeno-associated virus (AAV) that contains at least one modification that reduces the antigenicity of the virus. The invention further relates to the production of the structural protein and to its use.--

IN THE CLAIMS:

Claims 97, 99 and 100 have been amended; see attached complete claim listing.

Examiner's Comment

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

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The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Applicant is now required to submit a substitute declaration or oath to correct this deficiency. The substitute oath or declaration must be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability" (PTO-37). Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136. Failure to timely file the substitute declaration (or oath) will result in **ABANDONMENT** of the application. The transmittal letter accompanying the declaration (or oath) should indicate the date of the "Notice of Allowance" (PTOL-85) and the application number in the upper right hand corner. Note that an application data sheet that indicates the corrected address of Anne Girod will be sufficient to overcome this objection to the oath/declaration such that a substitute oath/declaration will not be required.

The specification was amended to include an abstract. Claim 97 was amended to correct Markush group language. Claims 99 and 100 were amended to correct minor typographical errors. The rejection of claims 91 and 94-98 under 35 U.S.C. 102(b) as being anticipated by Mamounas *et al.* (WO 97/38723, herein, "Mamounas"), evidenced by Rutledge *et al.* (*Journal of Virology*, 1998, 72(1):309-319, "Rutledge"), is withdrawn in view of Applicant's persuasive arguments submitted January 22, 2007. The Office has considered Applicant's Exhibit I, and agrees that the numbering that the examiner used was not correct. Therefore, Mamounas' suggestion to modify in the region 239-244 of VP3 is not the same as the region of Applicant's SEQ ID NO: 4.

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Conclusion

3. Claims 91 and 94-100 as amended are allowable.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 3/27/07
STACY B. CHEN
PRIMARY EXAMINER

COMPLETE CLAIM LISTING WITH EXAMINER'S AMENDMENT

1-90. (Canceled)

91. (Previously presented) A method for reducing the antigenicity, relative to wild-type AAV, of an AAV particle, the method comprising introducing at least one modification into a structural protein of AAV, the structural protein being selected from the group consisting of AAV VP1, VP2, and VP3, wherein the modification brings about a reduction in the antigenicity of the virus relative to wild-type AAV and wherein the modified structural protein forms AAV particles and the AAV having the modified structural protein retains infectivity, and further wherein the modification(s) is/are located directly adjacent to at least one amino acid in a sequence selected from the group consisting of YKQIS SQSGA (SEQ ID NO: 2), YLTLN NGSQA (SEQ ID NO: 3), YYLSR TNTPS (SEQ ID NO: 4), EEKFF PQSGV (SEQ ID NO: 5), NPVAT EQYGS (SEQ ID NOS: 6, 7), LQRGN RQAAT (SEQ ID NO: 8), and NVDFT VDTNG (SEQ ID NO: 9).

92-93. (Canceled)

94. (Previously presented) The method as claimed in claim 91, wherein at least one of said modifications is based on a covalent or noncovalent linkage to the structural protein of one or more compound(s) selected from the group consisting of biotin, a mono- or oligosaccharide, a hydroxide group, an F_{ab} fragment, and one or more amino acid(s) or amino acid sequence(s).

95. (Previously presented) The method as claimed in claim 91, wherein the modification is a mutation selected from the group consisting of a point mutation, a mutation of more than one amino acid, one or more deletions, one or more insertions, and a combination of these mutations.

96. (Previously presented) The method as claimed in claim 91, wherein the modification comprises a protein or a peptide inserted into the structural protein.

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97. (Currently amended) The method as claimed in claim 96, wherein the inserted protein or peptide is selected from the group consisting of a cell membrane receptor ligand, a Rep protein or peptide, an integrin, a cytokine or receptor-binding domain of a cytokine, a growth factor, a single-chain antibody, a single-chain antibody binding to a cell surface receptor, a catecholamine, protein A or a part thereof, protein G or a part thereof, and an anti-Fc antibody or a part thereof.

98. (Previously presented) The method as claimed in claim 91, wherein the structural protein comprises at least one other modification.

99. (Currently amended) The method as claimed in claim 91, wherein at least one of the modifications is/are located directly adjacent to at least one amino acid in the sequence LQRGN RQAAT (SEQ ID NO: 8).

100. (Currently amended) The method as claimed in claim 91, wherein at least one of the modifications is/are located directly adjacent to at least one amino acid in the sequence NVDFV VDTNG (SEQ ID NO: 9).